

510(k) SummaryK051956

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This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: JUNE 17, 2005

1. Submitter:

	Company
Name	SOMETECH INCORPORATED
Address	Byucksan Digital Valley III 212-13 Guro-dong Guro-gu Seoul, 152-050 Korea
Phone	+82 2 547-3422
Contact	Young-Soo Seol

2. Device:

Proprietary Name - Dr. OPPEL ST-501

Common Name - Electrosurgical unit and accessories

Classification Name - Electrosurgical cutting and coagulation device and Accessories

3. Predicate Device:

Aaron 900 High Frequency Desiccator/Handpiece, Aaron Medical Industries, K000961

Aaron Reusable Electrosurgical Electrode, Aaron Medical Industries, K014201

Surgitron 120 IEC, Ellman International, Inc., K013255

4. Classifications & Citations:

21CFR 878.4400, GEI

Class 2

510(k) Guidance Document for General Surgical Electrosurgical Devices

5. Description:

Dr. OPPEL ST-501 is a electrosurgical unit using high frequency current to cut and/or coagulate tissue. It consists of Electrosurgical Unit generator, Handpiece, Electrodes, a cable for disposable patient plate and foot switch. It is a compact source of high power RF energy to be employed for a variety of radiosurgery procedures. This action is achieved by front panel selection of power level and time. All selection is effected through push buttons and lamps that give the operator feedback of status. The final output power control is made through foot and/or hand switches.

Both Monopolar and Bipolar electrodes are provided. Monopolar electrodes have needle, ball, loop and blade types. Electrodes are supplied non-sterile and reusable.

6. Indication for use:

Dr. OPPEL ST-501 is intended for the removal and destruction of skin legions and the coagulation of tissue. Non-sterile and reusable electrodes are used in conjunction with an electrosurgical handpiece and generator.

7. Technological characteristics

Feature	Dr. OPPEL ST-501	Aaron 900 High Frequency Desiccator/ Handpiece	Aaron Reusable Electrosurgical Electrode	Surgitron 120 IEC
Indications for use	Dr. OPPEL ST-501 is intended for the removal and destruction of skin lesions and the coagulation of tissue. Non-sterile and reusable electrodes are used in conjunction with an electrosurgical handpiece and generator.	The Aaron 900 High Frequency Desiccator and Handpiece are intended for the removal and destruction of skin lesions and the coagulation of tissue.	Aaron Reusable Electrosurgical Electrodes are non-sterile, reusable electrosurgical electrodes, used in conjunction with an electrosurgical handpiece and generator to deliver RF energy used to cut and excise tissue or to coagulate blood vessels during surgery.	1. Cutting - Snoring, Submucosal palatal shrinkage, etc. 2. Blended Cutting and Coagulation - Snoring, Submucosal palatal shrinkage, etc. 3. Hemostasis - Control of Bleeding, Epilation, etc. 4. Fulguration - Basal Cell Carcinoma, Papilloma, etc. 5. Bipolar - Pinpoint, Precise Coagulation, etc.
Design specification	IEC601-2-2 ANSI/AAMI HF-18	IEC601-2-2 UL2601-1	N/A	IEC601-2-2 UL544
Output energy	100 Watt at 200Ω	30 Watt	N/A	120 Watt
Output waveform	4.0 MHz Partially rectified	550 kHz Partially rectified	N/A	4.0 MHz Continuous, Fully rectified, Partially rectified, 1.7MHz fulguration
Delivery system	Monopolar and Bipolar	Monopolar and Bipolar	N/A	Monopolar and Bipolar
Tip configuration	Needle Blade Ball Loop Bipolar Forceps	N/A	Needle Blade Ball Loop Bipolar Forceps	Needle Blade Ball Loop Bipolar Forceps
Sterilization method	Non-sterile	N/A	Non-sterile	Non-sterile
Standard	IEC601-1 IEC601-1-2 IEC601-2-2 ANSI/AAMI HF18	UL2601-1 EN60601-1-2 IEC601-2-2	N/A	UL2601 IEC601-1 IEC601-2-2

8. Similarities to, and differences from, the above predicate devices:

Dr. OPPEL ST-501 is similar to the above predicate devices based on the intended use, technology used, the claims, the material composition employed and performance characteristics. The differences from the predicate devices are amount of output energy and output waveform.

9. Conclusions :

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, FDA's "510(k) Guidance Document for General Surgical Electrosurgical Devices" and based on the information provided in this premarket notification Sometech Incorporated concludes that Dr. OPPEL ST-501 is safe and effective and substantially equivalent to predicate devices as described herein.

END



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sometech Incorporation
c/o Mr. Marc M. Mouser
Office Coordinator
Underwriters Laboratories, Inc.
Laboratory and Testing
2600 N.W. Lake Road
Camas, Washington 98607-8542

Re: K051956

Trade/Device Name: Dr. OPPEL ST-501
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: II
Product Code: GEI
Dated: August 22, 2005
Received: August 25, 2005

Dear Mr. Mouser:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson".

Mark N. Melkerson *for*
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number K 051956

Device Name: Dr. OPPEL ST-501

Indication for use: Dr. OPPEL ST-501 is intended for the removal and destruction of skin lesions and the coagulation of tissue. Non-sterile and reusable electrodes are used in conjunction with an electrosurgical handpiece and generator.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21CFR801 Subpart D) (21CFR801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nir R. D. G. L.
(Division Sign-Off) *for M.N.M.*

Division of General, Restorative,
and Neurological Devices

510(k) Number K051956